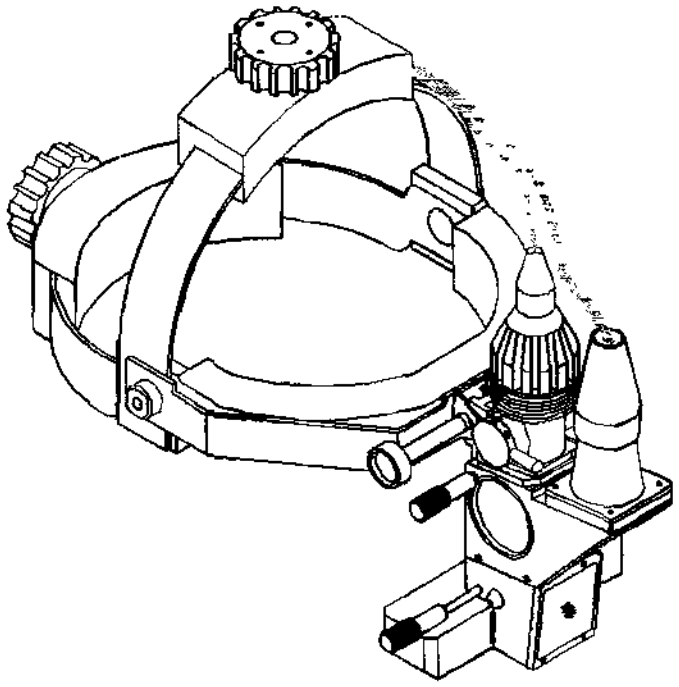
LASER INDIRECT OPHTALMOSCOPE (LIO)
Model OHL 5.1



User's Guide

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LIO-LASER INDIRECT OPHTALMOSCOPE MODEL 0HL 5.1

1 - SAFETY INFORMATION

1.1 - Eye Protection from the treatment laser (810 nm)

A nonmoving eye filter is permanently fixed within the Laser Indirect Ophthalmoscope to protect the physician's eyes from back reflections of the treatment beam.
While the LIO is in use, all attending persons in the treatment room should wear safety glasses marked for use with diode lasers (810 nm). These glasses can be purchased from Eyetec or from other suppliers See appendix B for details
The patient's eye not undergoing treatment should be protected with a patch

1.2 - Protection from the Red Diode Aiming Laser

The red aiming beam can be continuously adjusted from zero milliwWatts to a maximum power of 0,95 milliWatts If the beam is viewed directly at the maximun aiming laser of 0,95 milliWatts, retinal exposure durations greater than 4.1 seconds will exceed Class I limits A Class I is considered safe for unlimited retinal exposure durations

1.3 - Reflection Hazards

Metal objects will reflect the laser beams. These reflection hazards can exist several feet beyond the LIO. Therefore, the laser beam should not be directed at unintended objects, and non reflective instruments should be used whenever possible

1.4 - Explosion Hazard

Never operate the Eyetec Laser Indirect Ophthalmoscope in the presence of flammables or explosives, such as volatile anesthesics, alcohol , etc.

2 - BASIC OPERATION

Your LIO is used in conjunction with your Diode Laser Photocoagulators produced by Opto Eletronica or Iris Medical Instruments
For information on use of theses Photocogulators , consult the user manual
Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous emission of laser energy
When changing delivery systems, be sure to place the protective cap on the fiber input because debris colected on the input face degrades transmission.

2.1 - Headpiece Fit and Adjustments

The LIO must fit properly on the physician's head, and the viewing system must be set at the proper angle These adjustments will differ for each physician. Follow the instructions in this manual to achieve a secure but comfortable fit For physicians who wear glasses , they must be worn while using the ophthalmoscope

2.2 - Adjusting the head size

The LIO has two adjusting bottoms: one is at the back for controlling the headpiece's circuference, and the other bottom is for controlling the headpiece height.

Adjusting the Angle of Aerial View – The typical separation between the physician and the fundus image during an indirect ophthalmoscope procedure is 14 inches Place a temporary viewing target (such as your hand) about 14 inches away from the ophthalmoscope, then tighten the Angle Adjustment knob to secure the optical unit

2.3 - Adjusting Interpupillary Distance

Use the finger tabs on the underside of the LIO and slide each eyepiece to adjust the interpuppillary distance. Close one eye and then the other. Adjust the separation until each eye sees the entire target.

2.4 - Adjusting the Illumination Light and Aiming Beam

1- Place the laser in a convenient location and plug the power cord into a convenient electrical outlet Connect the Foot Switch and Remote Interlock as described in Section 4.
2- Remove and store the protective caps from the laser port and the fiber optic cable Connect the fiber optic cable by inserting the connector end into the Fiber Port and tightening the finger nut clockwise. Do not over tighten the connector. Insert the illumination cable plug into the illumination power jack on the front of the Photocoagulator . Press in firmly while rotating slightly to seat connector properly.
3- Select Treat mode on then Photocoagulator Verify that both a white illumination light beam and a red aiming beam are emitting from the laser aperture.
4- To adjust the illumination intensity, turn the Illumination Brightness Control knob clockwise to increase brightness and counterclockwise to decrease brightness
5- To adjust the red aiming beam intensity, refer to the manual of Photocoagulator that is been used
6- To adjust the vertical position of the white illumination light, rotate the Illumination Mirror Adjustment knob on the LIO to center the white light within the field of view If the illumination beam appears to be displaced to one side, move both interpupillary Distance Adjustment finger tabs in the same direction until the light is centered
7- To adjust the vertical location of the red aiming beam, turn the Laser Mirror Adjustment knob on the LIO to position the red laser beam within the field of view The treatment beam is delivered to the site illuminated by the red aiming beam

2.5 - System Use

1 – Turn on the Photocoagulator and the illumination power supply;
2 – Select the desired laser power and exposure time on the Photocoagulator control panel,
3 – Obtain the optimal aspheric lens position and locate the area of the retina to be treated;

4 – Direct the red aiming beam to the target site by moving your head side to side and up and down,
5 – Move your head closer to and farther from the patient to find the optimum treatment beam focus,
6 – Depress the Foot Switch to activate the Photocoagulator treatment beam

2.6 - System Turn-Off

1 – Turn off the LIO and the illumination power supply;
2 – Store the examination lens in its container,
3 – Remove the LIO fiber from the Photocoagulator and cover the input fiber face and the Photocoagulator laser port with their protective caps,
4 – Store the LIO in its carrying case.

3 - PHYSICIANS INSTRUCTIONS

3.1 - Indications for Clinical Use

The Eyetec Laser Indirect Oftalmoscope is indicated for retinal photocoagulation of the following ophthalmic conditions:

1 – Proliferative and nonproliferative diabetic retinopathy,
2 – Retinal tears;
3 – Lattice degeneration,
4 – Localized retinal detachments;
5 – Retinopexy

3.2 - Contraindication

The LIO is not indicated for cases involving laser photocoagulation within the arcades.

Warnings: The LIO mounts on a headpiece worn on the physician's head. The physician must avoid making abrupt movements while the system is delivering laser

The LIO headpiece becomes quite warm in use. Care should be taken when making adjustments or while handling the Ophthalmoscope during or immediately after use.

All support personnel in the operating room should wear appropriate laser safety glasses while the ophthalmoscope is in use

Do not use durations of less than 200 milliseconds With short durations and high powers, there is a greater risk of choroidal hemorrhage.

When establishing threshold lesions be sure to keep the aiming beam in sharp focus so that the power density on the retina does not increase

3.3 - Directions for Use

Typical power settings used for the LIO are adjustable from 250 milliWatts to 1000 milliWatts, according to the patient's pathology and retinal pigmentation Pulse durations should typically be set at between 200 and 600 milliseconds. If you are uncertain of retinal response, always start with the lower power settings and increase the power until you observe satisfactory clinical lesions. Because the red aiming beam and the infrared treatment beam are parfocal (that is, they come to focus at the same optical point), make sure that the aiming beam is always in sharp focus during laser delivery An out-of-focus spot may not produce a clinically satisfactory lesion

3.4 - Treatment Suggestions

Place the patient in a supine or near supine position,

Position you head 15 to 20 inches from the patient's eye;

Direct the white illumination light and the red aiming beam into the patient's eye by moving your head. Do not readjust the ophthalmoscope;

Hold the laser-coated aspheric lens, while ringed side toward the patient, so that the patient's pupil is centered in the lens,

Positioning the aspheric lens 55 mm from an emmetropic eye should produce a magnified aerial image of the fundus, A myopic eye will require the examination lens to be slightly closer (the hyperopic eye slightly farther) to obtain the desired fundus image.

Tissue response to laser light is primarily determined by power density. Power density (Watt/cm^2) can be defined as laser power (Watts) divided by the area (cm^2) of the illuminated spot. Therefore, power density can be increased either by increasing laser power or by decreasing the spot size.

Note: The relationship between spot size and resultant power density is not linear Halving the spot size quadruples the power density The laser clinician must understand the relationships between spot size, laser power, power density, and laser/tissue interaction before using a diode laser system and the Laser Indirect Ophthalmoscope

4 - MAINTENANCE

4.1 - Routine Maintenance

The LIO is an extremely reliable laser delivery system However, as with any optical device, it should be handled with care
Observe the following guidelines:

- Do not bend the optical fiber into loops shorter than 8 inches Instead, loosely drape or coil it on a flat surface. Keep the fiber away from aisles where it may be easily stepped on.

- Keep the dust window and the aspheric lens free of fingerprints Clean these surfaces as indicated below

4.2 - Cleaning

- Wipe headpieces surfaces with a soft cloth dampened with a mild detergent.
- Follow the manufacture's instructions for using and cleaning the aspheric lens.
- Several times a year, inspect the binocular eyepieces and clean them by wiping them gently with lens tissue moistened with lens cleanner

4.3 - Clean the dust window as follows:

1 – Wrap a lens tissue (Kodak or equivalent) around one end of a cotton-tipped swab.
2 – Place several drops of 100% ethanol, 100% methanol, or high-grade acetone in the tissue.
3 – Wipe the lens gently with the swab to remove all dust debris.
4 – If the surface is still no clean, put a clean lens tissue around the end of the swab and gently wipe it again.

4.4 - Changing the Illumination Lamp

1 – Turn off the Illumination Power Supply and remove the cable connection
2 – Remove the lamp retaining cap.
3 – Remove the burned-out lamp
4 – Replace it with an identical type of lamp, aligning the key on the lamp base with the slot in the LIO. Do not touch the lamp's glass envelope because this will reduce the life of the lamp. Remove accidental fingerprints from the lamp envelope with a Q-tip and methanol
5 – Replace the lamp cap
6 – Reconnect the cable to the Illumination Power Supply or store it for future use

4.5 - Changing The Fuse in the auxiliary Illumination Power Supply

1 – Unplug the power cord from the illumination box at the wall socket.
2 – Remove the fuse holder from the power supply.
3 – Remove the blown fuse and replace it with a fuse with the same rating

5 - TROUBLESHOOTING GUIDE

The following troubleshooting guide will help you to locate and correct a malfunction should the LIO not operate properly

Problem / Possible Cause	Solution
No illumination light. Illumination spot size and filter selector levers are in between detents	Ophthalmoscope illumination housing is warm, but no light is visible. Reset levers to proper detent.
The illumination cable is not connected to the console or auxiliary power supply	Connect cable per Section 10 "Basic Operation"
The illumination box is not plugged in and/or its switch is not turned on	Plug the illumination box power cord into the wall socket. Turn the unit on. Set the Illumination Brightness Control knob to the intermediate position.
The illumination lamp does not work	Replace the lamp
The illumination power supply fuse is not burned out	Check and replace the fuse if necessary
The aiming beam is large or out of focus on the patient's retina	Adjust distance from the LIO's headpiece to the examination lens The aiming beam should be sharply defined
Treatment lesion are variable or intermittent	The LIO may be slightly out of focus, wich decreases power density. Readjust your working distance as above. A poorly centered laser beam may be clipping on the examination lens or on the patient's iris Adjust the laser beam control on the LIO to center the aiming beam in the white light field. Laser treatment parameters may be too close to the tissue response threshold for consistent response Increase laser power and/or exposure duration. Alternatively, laser power density may be increased by selecting a lower diopter examination lens (that is, by using a 15D rather than 20D) to reduce laser spot size on the retina. This will also alter the physician's field of view.

Eyetec Customer Service

If you have questions regarding the adjustment or operation of the Laser Indirect Ophthalmoscope, please call the Customer Service Number :55-16-274-3012.

6 - PRODUCT SPECIFICATIONS

Laser System Compatibility	Diode Laser Photocoagulators: Opto and Iris
Treatment Beam	Laser Diode 800-825 nm, 0–1 100 mw (adjustable laser power)
Aiming Beam always on	Red Laser Diode. 0-0,95 mw, Adjustable, delivered out of LIO Coaxial and parfocal with Treat beam and when in Treat mode.
Weight (head)	845 grams
Diameter of Laser's Spot	1.0 mm
Distance to Aerial Image	300 mm
Temperature Range	10° C to 40° C
Relative Humidity	5%-95%, non condensing
Power Supply	115/220 Vac automatic, fuse, etc
Carrying case dimensions	480 mm x 350 mm x 160 mm

Optional Accessories

Specially laser-coated examination lenses (VOLK or OCULAR) are recommended for use with the LIO. Twenty-diopter lenses (20D), which provide a clear aperture of 51 millimeters and a 45° retinal field of view, are typically used, a 15 diopter and 2 2 pan-retinal lenses are also available.

REFERENCES.

1 – Fribert TR. *Clinical experience with a binocular indirect ophtalmoscope laser delivery system* Retina· 7:28-31,1987

2 – Fribert TR and Eller AW *Pneumatic repair of primary and secondary retinal detachments using a binocular indirect ophtalmoscope laser delivery system.* Ophthalmol 95:187-193, 1988

3 – Fribert TR *Principals of photocoagulation using binocular indirect ophthalmoscope laser delivery systems.* Intl. Ophth Clinics. 30.89-94, 1990

7 - WARRANTY

This equipment, manufactured by OPTO Eletronica S.A., is warranted for the first purchaser, under normal operating conditions, against manufacturing or material defects during the period of one (1) year after the purchase date. The warranty shall not be valid if the equipment is damaged by accident or improper use, or if it was violated or modified by non-authorized companies or people. This warranty disclaims OPTO from any other obligation, express or implied, and does not cover any other warranty.

Note : If the equipment shows any factoring damage or working unproperly in the warranty period (12 months); the expenses of equipment transport, technical's accomodation and travel, will be by client responsibility. The job, pieces and component changes expenses, will be by factoring responsibility.

Important

The equipment owner should prove that the equipment is within the warranty period by submitting the purchase document (invoice). Therefore, keep it safe place.